

## **REMARKS**

Claims 21-35 are presently pending in the case. Claims 28-35 have been added. The new claims are supported by the specification and claims as originally filed.

Reconsideration of the present case in view of the above amendments and the remarks herein is requested.

### **Claim rejections under 35 USC 103(a)**

The Examiner rejected claims 21-27 under 35 USC 103(a) as being unpatentable over European Patent Application 0 808 635 to Howlett (hereinafter Howlett). The rejection is traversed.

Howlett does not render Applicant's invention as set forth in claim 21 unpatentable because it does not teach or suggest all features positively recited in the claim. Claim 21 is to a device for controlling the delivery of an aerosolized active agent to the lungs comprising, inter alia, a flow resistance modulator that provides a high flow resistance of at least  $0.4 \text{ (cm H}_2\text{O)}^{1/2} / \text{SLM}$ . Howlett does not disclose a flow resistance modulator that provides a high flow resistance of at least  $0.4 \text{ (cm H}_2\text{O)}^{1/2} / \text{SLM}$ . Instead, Howlett discloses an inhaler with an air flow controller which provides an air flow of a predetermined rate (column 2 lines 1-16). The air flow controller of Howlett is not disclosed as providing a high flow resistance of at least  $0.4 \text{ (cm H}_2\text{O)}^{1/2} / \text{SLM}$ . Therefore, all elements of claim 21 are not taught or suggested by the reference.

In addition, it would not have been obvious to one of ordinary skill in the art to modify Howlett to arrive at the invention of claim 21. In particular, it would not have been obvious to provide Howlett's device with a high flow resistance of at least  $0.4 \text{ (cm H}_2\text{O)}^{1/2} / \text{SLM}$ . Howlett does not teach providing a high flow resistance. In fact, Howlett specifically teaches the desirability of controlling the flow rate at 30 to 60 liters per minute (column 3 lines 43-50). One of ordinary skill in the art would recognize that a user of the device may have difficulty maintaining a flow rate of 30 to 60 liters per minute using a device having a flow resistance of at least  $0.4 \text{ (cm H}_2\text{O)}^{1/2} / \text{SLM}$ , and would not find it obvious to provide such a flow resistance.

Thus, when considering the teachings of the reference as a whole, Howlett teaches away from a high flow resistance. Accordingly, one of ordinary skill in the art would not find it obvious to modify the Howlett device to provide a flow resistance of at least  $0.4 \text{ (cm H}_2\text{O)}^{1/2} / \text{SLM}$ , and Howlett does not render claim 21 unpatentable.

Furthermore, the Examiner's suggestion that "mere routine experimentation and observation" would arrive at the claimed flow resistance is not consistent with the teachings of the reference. First, there is no teaching or suggestion in Howlett that any experimentation and observation is needed for the Howlett device. Secondly, Howlett teaches the desirability of a flow rate of 30-60 liters per minute. Thus, even if performed, the artisan's experimentation and observation would be aimed at achieving the desired flow rate taught, not aimed at achieving a high flow resistance as disclosed by Applicant and which the person of ordinary skill in the art would not have had the benefit of reading. Thus, the Examiner is using impermissible hindsight reasoning, which is contrary to the teachings of Howlett, in suggesting that Applicant's invention of claim 21 is rendered obvious by the reference.

By including a flow resistance modulator that provides a high flow resistance of at least  $0.4 \text{ (cm H}_2\text{O)}^{1/2} / \text{SLM}$ , Applicant's invention has several advantages over prior art devices, such as Howlett. For example, as discussed in Applicant's specification, the high flow resistance may be used to provide an active agent to a patient in a manner that increases the bioavailability of the agent. This unexpected advantage resulting from the high flow resistance is further evidence of the non-obviousness of the feature.

Claims 22-27 depend from and include the limitations of claim 21. Therefore, Howlett does not render claims 22-27 unpatentable for at least the reasons discussed above. In addition, claim 24, for example, further recites that the high flow resistance corresponds to a flow rate of 15 liters per minute or less. Since Howlett teaches a flow rate of 30-60 liters per minute, it does not teach or suggest a flow resistance corresponding to a flow rate of 15 liters per minute or less.

## **New Claims**

Claims 28-35 have been added to define other aspects of Applicant's invention.

## Information Disclosure Statement

Applicant is filing herewith an information disclosure statement in compliance with MPEP section 609. Indication of consideration of the references provided is requested. In addition, information disclosure statements were filed on July 28, 2000, on February 26, 2001, and on April 3, 2001. Applicant has included herewith copies of the statements and copies of the postcard returned by the Patent Office indicating that the information disclosure statements were received. Applicant request indication of the consideration of the references cited in these information disclosure statements as well.

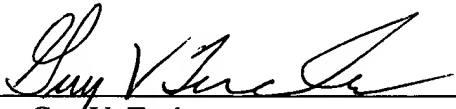
## Conclusion

The claims are allowable for the reasons given above. Thus, the Examiner is respectfully requested to reconsider the present rejections and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

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**MARKED-UP VERSION OF AMENDMENTS**

Claims 28-35 are new.